



**Executive Offices**

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K963066

**510(k) SUMMARY**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

SEP 27 1996

The assigned 510(k) number is:

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**Device Name**

Proprietary Name: Mentor Injection Port Detector

Common Name: Injection Port Detector

**Substantial Equivalence Claim**

The Mentor H/S Injection Port Detector is similar in indications, design and features to the Mentor Accu-Tec™ Injection Port Detector (K905484).

**Indications For Use**

The Mentor H/S Injection Port Detector is used to detect Mentor Tissue Expander remote and integral injection ports. The device is nonsterile and for postoperative use only.

**Device Description**

The Mentor H/S Injection Port Detector is a hand-held battery operated, rechargeable unit which detects the stainless steel needle guard located inside remote and integral tissue expander injection ports. When not in use, the device rests in a charging cradle to maintain full charge.

The device contains electro magnetic coils and circuitry which detects changing magnetic fields. The presence of an injection port near the coils causes a change in the magnetic field, which in turn induces a current in the coils. An LED display indicates when the center of the injection port has been located.

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